



Please type a plus sign (+) inside this box →

PTO/SB/08A (08-00)

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				Application Number	10/658,782
				Filing Date	September 8, 2003
				First Named Inventor	Arcangel et al.
				Group Art Unit	1651
				Examiner Name	Not Assigned
Sheet	1	of	2	Attorney Docket Number	PP19199.002 (2300-19199)

---

**U.S. PATENT DOCUMENTS**

---

## FOREIGN PATENT DOCUMENTS

Examiner Signature	m. mcfarland	Date Considered	July 27, 2004
--------------------	--------------	-----------------	---------------

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**1 Unique citation designation number.**

<sup>2</sup> See attached Kinds of U.S. Patent Documents.

<sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3).

For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible.

<sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

Please type a plus sign (+) inside this box →

PTO/SB/08A (08-00)

Substitute for form 1449A/PTO				<i>Complete if Known</i>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b> <i>(use as many sheets as necessary)</i>				<b>Application Number</b>	10/658,782
				<b>Filing Date</b>	September 8, 2003
				<b>First Named Inventor</b>	Arcangel et al.
				<b>Group Art Unit</b>	1651
				<b>Examiner Name</b>	Not Assigned
Sheet	2	of	2	Attorney Docket Number	PP19199.002 (2300-19199)

Examiner Signature		Date Considered	
-----------------------	--	--------------------	--

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number.

Applicant is to place a check mark here if English language Translation attached.

Mail Stop Patent Application  
 COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

FORM PTO-1449 (Modified)  
 LIST OF PATENTS AND PUBLICATIONS  
 FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
 (Use several sheets if necessary)  
 Sheet 1 of 4

In the Application of ARCANGEL et al.

Serial No.: Art Unit: Unassigned

Filed: On even date  Examiner: Unassigned

Title: HCV ASSAY

U.S. PATENT DOCUMENTS

Exam. I nit.	Ref. Desig.	Document No.	Date	Name	Class	Sub Class	Filing Date
<i>mm</i>	A1	5,350,671	September 27, 1994	Houghton et al.			
<i>mm</i>	A2	5,712,087	January 27, 1998	Houghton et al.			
<i>mm</i>	A3	5,843,752	December 1, 1998	Dasmahapatra et al.			
<i>mm</i>	A4	5,871,904	February 16, 1999	Kashiwakuma et al.			
<i>mm</i>	A5	5,990,276	November 23, 1999	Zhang et al.			
<i>mm</i>	A6	6,171,782	January 9, 2001	Houghton et al.			

FOREIGN PATENT DOCUMENTS

Exam. Init.	Ref. Desig.	Document No.	Publication Date	Country or Patent Office	Class	Sub Class	Translation YES NO
<i>mm</i>	B1	WO 93/00365 ✓	January 7, 1993	PCT			
<i>mm</i>	B2	WO 94/01778 ✓	January 20, 1994	PCT			
<i>mm</i>	B3	WO 97/44469 ✓	November 27, 1997	PCT			

Examiner:

Date Considered:

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Mail Stop Patent Application  
 COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

FORM PTO-1449 (Modified)  
 LIST OF PATENTS AND PUBLICATIONS  
 FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
 (Use several sheets if necessary)  
 Sheet 2 of 4

In the Application of ARCANGEL et al.

Serial No.: Art Unit: Unassigned

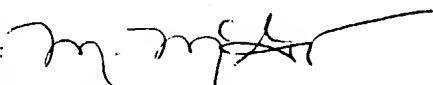
Filed: On even date  Examiner: Unassigned

Title: HCV ASSAY

mm	B4	318,216	✓ May 31, 1989	EPO				
mm	B5	388,232	✓ September 19, 1990	EPO				
mm	B6	0450931B1	✓ October 9, 1991	EPO				
mm	B7	0472207A2	February 26, 1992	EPO				

OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, etc.)

Exam. Init.	Ref. Desig.	Description
mm	C1	BELD et al., "Evaluation of automated RNA-extraction technology and a qualitative HCV assay for sensitivity and detection of HCV RNA in pool-screening systems," <i>Transfusion</i> 40:575-579, 2000
l	C2	Chen et al., "Human and murine antibody recognition is focused on the ATPase/helicase domain, but not the protease domain of the hepatitis C virus non-structural 3 protein," <i>Hepatology</i> 28:219-224, 1998
l	C3	Chien et al., "Diagnosis of Hepatitis C Virus (HCV) Infection Using an Immunodominant Chimeric Polyprotein to Capture Circulating Antibodies: Reevaluation of the Role of HCV in Liver Disease," <i>Proc. Natl. Acad. Sci. U.S.A.</i> 89:10011-10015 (1992)
l	C4	Chien et al., "Use of Recombinant HCV Antigen in the Serodiagnosis of Hepatitis C Virus Infection: Significant Improvement in HCV Antibody Detection as Compared with the First Generation HCV C100-3 ELISA and the Synthetic Peptide EIA Tests," <i>Jorunal of Gastroenterology Hepatology</i> 8:S33-39 (1993)

Examiner: 

Date Considered: July 27, 2004

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Mail Stop Patent Application  
 COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

FORM PTO-1449 (Modified)  
 LIST OF PATENTS AND PUBLICATIONS  
 FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
 (Use several sheets if necessary)  
 Sheet 3 of 4

In the Application of ARCANGEL et al.

Serial No.: Art Unit: Unassigned

Filed: On even date  Examiner: Unassigned

Title: HCV ASSAY

Exam. Init.	Ref. Desig.	Description
<i>mm</i>	C5	Chien et al., "Distinct subtypes of hepatitis C virus defined by antibodies directed to the putative core, NS4, and NS5 region polypeptides," <i>Virol. Hepatitis and Liver Disease</i> :320-324, 1994
<i>l</i>	C6	Choo et al., "Isolation of a cDNA Clone Derived from a Blood-Borne Non-A, Non-B Viral Hepatitis Genome," <i>Science</i> <u>244</u> :359-362 (1989)
<i>l</i>	C7	Choo et al., "Hepatitis C Virus: The Major Causative Agent of Viral Non-A, Non-B Hepatitis," <i>British Medical Bulletin</i> <u>46</u> (2):423-441 (1990)
<i>l</i>	C8	Cruse et al., <i>Illustrated Dictionary of Immunology</i> , CRC Press, Boca Raton FL, 1995, p76
<i>l</i>	C9	Ebeling et al., "Recombinant Immunoblot Assay for Hepatitis C Virus Antibody as Predictor of Infectivity," <i>Lancet</i> <u>335</u> :982-983 (1990)
<i>l</i>	C10	Houghton et al., "Molecular Biology of the Hepatitis C Viruses: Implications for Diagnosis, Development and Control of Viral Disease," <i>Hepatology</i> <u>14</u> :381-388 (1991)
<i>l</i>	C11	Kotwal et al., "Detection of acute hepatitis C virus infection by ELISA using a synthetic peptide comprising a structural epitope," <i>Proc. Natl. Acad. Sci. USA</i> <u>89</u> :4486-4489, 1992
<i>l</i>	C12	Kuo et al., "An Assay for Circulating Antibodies to a Major Etiologic Virus of Human Non-A, Non-B Hepatitis," <i>Science</i> <u>244</u> :362-364 (1989)
<i>l</i>	C13	Pereboeva et al., "Hepatitis C Epitopes From Phage-Displayed cDNA Libraries and Improved Diagnosis with a Chimeric Antigen," <i>J. Medical Virology</i> <u>60</u> :144-151, 2000
<i>l</i>	C14	van der Poel et al., "Infectivity of Blood Seropositive for Hepatitis C Virus Antibodies," <i>Lancet</i> <u>335</u> :558-560 (1990)

Examiner:

Date Considered:

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Mail Stop Patent Application  
 COMMISSIONER FOR PATENTS  
 P.O. Box 1450  
 Alexandria, VA 22313-1450

FORM PTO-1449 (Modified)  
 LIST OF PATENTS AND PUBLICATIONS  
 FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT  
 (Use several sheets if necessary)  
 Sheet 4 of 4

In the Application of ARCANGEL et al.

Serial No.: Art Unit: Unassigned

Filed: On even date  Examiner: Unassigned

Title: HCV ASSAY

Exam. Init.	Ref. Desig.	Description
<i>m m</i>	C15	Van der Poel et al., "Confirmation of hepatitis C virus infection by new four-antigen recombinant immunoblot assay," <i>Lancet</i> 337:317-319, 1991
<i>L</i>	C16	Yao et al., "Molecular views of viral polyprotein processing revealed by the crystal structure of the hepatitis C virus bifunctional protease-helicase," <i>Structure</i> 7(11):1353-1363, 1999

Examiner:

Date Considered:

EXAMINER: Initial if citation considered whether or not the citation conforms with MPEP609. Draw a line through the citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Attorney Docket No. 2300-19199 (PP19199.002)

PATENT

Express Mail Label No.: EL 985 780 180 US  
Date of Deposit: *September 8, 2003*

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of ARCANGEL et al.

Serial No.: Examiner: Unassigned

Confirmation No.: Art Unit: Unassigned

Filed: On even date herewith

For: HCV ASSAY

---

Mail Stop Patent Application  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §1.97(b)**

In accordance with the duty of disclosure set forth in 37 C.F.R. §1.56,  
Applicant(s) hereby submits the following information in conformance with 37 C.F.R.  
§§1.97 and 1.98.

- Pursuant to 37 C.F.R. §1.98, a copy of each document cited in the attached Form PTO-1449 is enclosed.
- No copies of the publications listed on the attached Form PTO-1449 are being provided pursuant to 37 C.F.R. §1.98(d) because the publications were previously cited by or submitted to the Office in prior Application Serial No. \_\_\_\_\_ to which the above-identified application claims priority under 35 U.S.C. §120.
- Publication(s) \_\_\_\_\_ listed on the attached Form PTO-1449 were cited in a foreign search or examination report corresponding to \_\_\_\_\_ application serial no. \_\_\_\_\_ and mailed on \_\_\_\_\_.
- Enclosed is a copy of a non-English publication(s) \_\_\_. Pursuant to §609 of the M.P.E.P., Applicant submits the attached foreign search or examination report, which cites such non-English language publication(s).

- Enclosed is a copy of a non-English publication(s) \_\_\_. English language publication \_\_ (copy enclosed) claims priority from this non-English publication.
- Enclosed is an explanation of non-English publication(s) \_\_ for which an English translation is not available.
- Enclosed is an English translation of non-English publication(s) \_\_ cited in the attached Form PTO-1449.
- Enclosed is a copy of pending patent Application Serial No. \_\_\_\_.

This Information Disclosure Statement is filed with the herein application.

It is respectfully requested that the Examiner consider the above-noted information and return an initialed copy of the attached Form PTO-1449 to the undersigned.

Please direct all further written communications in this application to:

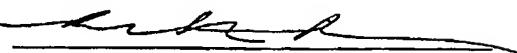
Marci Lillis, Ph.D.  
Chiron Corporation  
Intellectual Property – R440  
P.O. Box 8097  
Emeryville, CA 94662-8097.

Dated: 9/8/03

Respectfully submitted,

Chiron Corporation  
Intellectual Property – R440  
P.O. Box 8097  
Emeryville, CA 94662-8097  
Tel: (650) 493-3400  
Fax: (650) 493-3440

By:

  
Roberta L. Robins  
Reg. No. 33,208